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..Title

A RULE AND REGULATION relating to providing safe collection and disposal of unwanted drugs from residential sources through a producer provided and funded product stewardship plans, and adding a new chapter to BOH Title 3; enacted pursuant to RCW 70.05.060, including the latest amendments or revisions thereto.

..Body

BE IT ADOPTED BY THE KING COUNTY BOARD OF HEALTH:

SECTION 1. **Findings.**

[Section to be developed. The findings section will: summarize the reasons for establishing producer-funded and operated secure medicine return plans in King County; describe the Board of Health's intent for the Local Hazardous Waste Management Program's role in reviewing and providing guidance for the development and promotion of medicine return plans; identify the board's goal of establishing a secure medicine return system that is "fair and just" for all King County residents as consistent with K.C.C. sections 2.10.200 and 2.10.210; and summarize the educational and outreach activities the board encourages public and private entities to perform in support of secure medicine return plans.]

SECTION 2. Sections 1, 3, 4, 5, 6. 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, and 18 of this rule should constitute a new chapter on secure medicine return in BOH Title 3.

NEW SECTION. SECTION 3. **Citation.** This chapter may be cited and referred to, and shall be known as, the "King County Board of Health Secure Medicine Return Regulations."

NEW SECTION. SECTION 4. **Purpose and scope of chapter.**

A. This chapter is enacted as an exercise of the board of health powers of King County to protect and preserve the public health, safety, and welfare. Its provisions shall be liberally construed for the accomplishment of these purposes. This chapter governs the protection of human health and safety against the improper handling and disposal of leftover or expired medicines.

B. It is the specific intent of this chapter to place the obligation of complying with its requirements upon drug producers, stewardship organizations and other persons designated by this chapter within its scope, and any provision of or term used in this chapter is not intended to impose any duty whatsoever upon King County or any of its officers or employees, for whom the implementation or enforcement of this chapter shall be discretionary and not mandatory.

NEW SECTION. SECTION 5. **Definitions.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

A. "Collector" means a person that gathers unwanted covered drugs from covered entities for the purpose of collection, transportation and disposal.

B. 1. "Covered drug" includes all prescription and nonprescription drugs sold in any form and used by “covered entities”. This includes brand name and generic drugs.

2."Covered drug" does not include:

a. Vitamins or supplements;

b. Herbal-based remedies and homeopathic drugs, products, or remedies;

c. Cosmetics, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the federal food, drug, and cosmetic act. ;

d. Drugs for which producers provide a take-back program as part of a federal food and drug administration managed risk evaluation and mitigation strategy (21 U.S.C. Sec. 355-1);

e. Drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date of this section if the producer already provides a take-back program;

f. Medical devices, their component parts or accessories, or a covered drug contained in or on medical devices or their components parts or accessories; and

g. Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms.

C. “Covered entities” means residents of King County, including single and multiple family residences; and all non-business source entities that do not have an existing regulatory requirement for disposal of waste medicines. “Covered entities” does not include business generators of pharmaceutical waste, such as hospitals, clinics, doctor’s offices, veterinarian clinics, pharmacies, or airport security and law enforcement drug seizures.

D. "Director" means the director of the Seattle-King County Department of Public Health or the director's duly authorized representative.

E. "Drug wholesaler" means a corporation, individual, or other entity which buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

F. "Drugs" means:

1. Articles recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias;

2. Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

3. Substances, other than food, intended to affect the structure or any function of the body of humans or other animals; or

4. Substances intended for use as a component of any substances specified in subsection F.1., F.2. or F.3 of this subsection, but not including medical devices, their component parts or accessories, or a covered drug contained in or on medical devices or their component parts or accessories.

G. "Independent product stewardship plan" or "independent stewardship plan" means a plan for the collection, transportation, and disposal of unwanted covered drugs that is financed, developed, implemented and participated in by a producer or group of producers, operated by the participating producers or a stewardship organization, and approved by the director as an independent product stewardship plan.

H. "Local hazardous waste management program" means the King County local hazardous waste management program established under RCW 70.05.060, RCW 70.105.220 and BOH chapter 2.08.

I. "Manufacture" means as defined in RCW 18.64.011(15) the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include

the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, prepares, compounds, packages, or labels such substance or device.

J. "Manufacturer" is as defined in RCW 18.64.011(16)

a person, corporation, or other entity engaged in the manufacture of drugs or devices.

K. “Mail-back services” means a collection method for the return of unwanted covered drugs from covered entities utilizing prepaid and preaddressed mailing envelopes.

L. "Nonprescription drug" means any drugs that may be lawfully sold without a prescription.

M. "Person" means a firm, sole proprietorship, corporation, limited liability company, general partnership, limited partnership, limited liability partnership, association, cooperative, or other entity of any kind or nature.

N. "Prescription drug" means any drugs, including controlled substances under chapter 69.70 RCW, that are required by an applicable federal or state law or regulation to be dispensed by prescription only or are restricted to use by practitioners only.

O. "Producer” means a manufacturer who is engaged in the manufacture of a covered drug sold in or into King County.. Manufacture is defined as set forth in RCW 18.64.011(15). "Producer" does not include:

1. A retailer whose store label appears on a covered drug or the drug's packaging if the manufacturer from whom the retailer obtains the drug is identified under section 6.C of this rule; or

2. A pharmacist who compounds a prescribed individual drug product for a consumer; or

3. A wholesaler who is not also a manufacturer.

P. "Standard product stewardship plan" or "standard stewardship plan" means a plan for the collection, transportation, and disposal of unwanted covered drugs that is financed, developed, implemented and participated in by a group of producers, operated by the participating producers or a stewardship organization.

Q. "Stewardship organization" means an organization designated by a producer or group of producers to act as an agent on behalf of each producer to develop and implement and operate the standard product stewardship plan or an independent product stewardship plan.

R. "Unwanted covered drug" means any covered drug no longer wanted by its owner or that has been abandoned, discarded, or is intended to be discarded by its owner.

NEW SECTION. SECTION 6. **Product stewardship plans – Participation.**

A. Each producer shall participate in the standard product stewardship plan approved by the director, except that a producer may individually, or with a group of producers, participate in an independent product stewardship plan approved by the director.

B. The standard product stewardship plan and any independent product stewardship plan shall be approved by the director before collecting unwanted covered drugs.

C. By xx, 20xx [six months after R&R is passed], each producer of covered drugs sold in or into King County shall notify the director in writing of the producer's intent to

participate in the standard product stewardship plan or to form and participate in an independent product stewardship plan. A retailer whose store label appears on a covered drug or the drug's packaging must notify the director of intent to participate or provide written notification that the manufacturer from whom the retailer obtains the drug has provided its notice of intent to participate.

D. By xx, 20xx [nine months after R&R is passed], producers participating in the standard product stewardship plan or any independent product stewardship plan shall identify in writing to the director a plan operator, including the plan operator's telephone, mailing address and email contact information, who is authorized to be the official point of contact for the product stewardship plan.

E. A producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan shall:

1. By xx, 20xx [one year after R&R is passed], submit a proposed product stewardship plan as described in section 7 of this rule to the local director for review; the product stewardship plan must be approved by the director before collecting unwanted covered drugs;

2. Within three months after the director's approval of their stewardship plan or no later than xx, 20xx [eighteen months after R&R is passed], operate or participate in a product stewardship plan in accordance with this chapter;

3. Producers participating in a stewardship plan shall pay all administrative and operational fees associated with their product stewardship plan, including the cost of collecting, transporting, and disposing of unwanted covered drugs collected from covered entities, the recycling or disposal, or both, of packaging collected with the unwanted

covered drugs, promotion activities, and other producer responsibilities set forth in this chapter

4. Producers participating in a stewardship plan may enter into contracts and agreements with stewardship organizations, other service providers, or other entities as necessary, useful, or convenient to provide all or portions of their product stewardship plan;

5. A group of producers or stewardship organization may notify the director of any producer selling covered drugs in or into King County that is failing to participate in a product stewardship plan.

6. Producers participating in a stewardship plan may perform any other functions as may be necessary or proper to provide the product stewardship plan and to fulfill any or all of the purposes for which the plan is organized.

F. Submission dates and deadlines described in this section may be extended to a later date as approved in writing by the director.

G. After presenting official credentials and providing notice of an audit or inspection to determine compliance with this chapter or to investigate a complaint, the director may audit a producer's, group of producers', or stewardship organization's records related to a product stewardship plan or request the producer, group of producers, or stewardship organization to arrange for the director to inspect at reasonable times a product stewardship plan's or a collector's facilities, vehicles, and equipment used in carrying out the stewardship plan.

NEW SECTION. SECTION 7. **Product stewardship plans – Components.** The standard product stewardship plan or any independent product stewardship plan,

which must be developed and reviewed according to section 14 of this rule, shall include the following:

A. Contact information for all drug producers participating in the product stewardship plan.

B. A description of the proposed collection system to provide convenient ongoing collection service to covered entities in compliance with the provisions and requirements in section 8 of this rule.

C. A description of the handling and disposal system, including identification of and contact information for collectors, transporters, and waste disposal facilities to be used by the product stewardship plan in accordance with sections 8 and 10 and other provisions of this rule;

D. A description of how the stewardship plan will use existing providers of waste pharmaceutical services to the extent possible;

E. A description of the policies and procedures to be followed by persons in charge of unwanted covered drugs collected pursuant to the product stewardship plan, including a description of how all collectors, transporters and waste disposal facilities utilized shall ensure the collected, unwanted covered drugs are safely and securely tracked from collection through final disposal, and how all entities participating in the product stewardship plan shall operate under all applicable federal and state laws, rules and guidelines, including those of the United States drug enforcement agency, and how any pharmacy collection site will operate under applicable rules and guidelines of the state of Washington board of pharmacy;

F. A description of how covered drugs will be separated from packaging to the extent possible to reduce transportation and disposal costs, and how drug packaging will be recycled to the extent feasible;

G. A description of how patient information on drug packaging will be kept secure during collection, transportation, and disposal; and

H. A description of the public education effort and promotion strategy required in section 9 of this rule.

I. A proposal on the short term and long term goals of the product stewardship plan for collection amounts, education and promotion.

NEW SECTION. SECTION 8. **Product stewardship plans – Collection of covered drugs.**

A. This chapter does not require any person to serve as a collector in a product stewardship plan. A person may offer to serve as a collector, or may agree to serve as a collector in exchange for incentives or payment offered by a producer, group of producers or stewardship organization. Collectors may include law enforcement, retail pharmacies, and mail-back services, operating in accordance with state and federal laws and regulations for the handling of covered drugs, including those of the United States drug enforcement agency, and in compliance with this chapter. Any pharmacy collection site will operate under applicable rules and guidelines of the state of Washington board of pharmacy.

B. The collection system shall be convenient on an ongoing basis and adequately serve the needs of covered entities in both urban and rural areas, and shall provide equitable opportunities for all King County residents for the safe and convenient return of

unwanted covered drugs, including for people of color, low-income communities and those living in economically distressed and disadvantaged communities, people with limited English proficiency, and differentially abled and homebound populations.

C. In establishing and operating a product stewardship plan, a producer, group of producers or stewardship organization shall give preference to having pharmacies and law enforcement agencies serve as ongoing drop-off sites, and shall include, as collectors, any retail pharmacy or any law enforcement agency willing voluntarily to serve as a drop-off site for unwanted covered drugs and able to meet the requirements of this title. Drop-off sites shall accept covered drugs from covered entities during all hours that the retail pharmacy or law enforcement agency is normally operating for business with the public.

D. To ensure adequate collection opportunities, a stewardship plan's service goal is to provide a drop-off site within a fifteen miles radius for at least ninety percent of the county's residents, and one additional drop-off site for every thirty thousand residents of a city distributed to provide convenient and reasonably equitable access for residents within each city. If such service cannot be achieved through voluntary collectors providing ongoing drop-off sites, then periodic collection events operated by law enforcement or mail-back services, or a combination of these collection methods, shall be provided to improve convenience and availability of services.

E. Mail-back services shall be made available to differentially-able and home bound residents upon request through the stewardship plan's toll-free telephone number and web site, and through distribution of prepaid, preaddressed mailers to persons providing services to those residents.

F. The collection system for all unwanted covered drugs shall be safe, secure, and protect patient information. Ongoing drop-off sites shall utilize secure drop boxes in compliance with all applicable requirements of the United States drug enforcement agency and the state of Washington board of pharmacy.

NEW SECTION. SECTION 9. **Product stewardship plans – Promotion.**

A. A producer or producers shall promote the use of their product stewardship plan and the safe storage and use of the secure medicine return program for covered drugs so that collection options are widely understood by customers, pharmacists, retailers of covered drugs, and health care practitioners including doctors and other prescribers.

B. A producer or producers shall work with collectors participating in their product stewardship plan to develop clear, standardized instructions for residents on the use of drop boxes. The local hazardous waste management program may provide guidance to producers and collectors on the development of these instructions.

C. A producer or producers shall establish a toll-free telephone number and web site where collection options will be publicized and prepare educational and outreach materials describing where and how to return unwanted covered drugs to the product stewardship plan. These materials must be provided to pharmacies, health care facilities, and other interested parties for dissemination to residents. A producer or group of producers participating in the standard stewardship plan and any independent stewardship plans shall coordinate these promotional activities to ensure that residents can easily identify, understand and access the collection services provided by any stewardship plan.

D. A producer or producers shall annually evaluate the effectiveness of its outreach and product stewardship plan activities.

E. A producer or producers must conduct a survey of residents of King County to determine the percentage of residents that are aware of the product stewardship plan and to what extent residents find the plan convenient after the first full year of operation of the plan, and again after five and nine years of operation. Results of the survey shall be reported to the director and made available to the public on the stewardship plan's website.

F. [note: the language in subsection F will be moved to the Findings section because it lists encouragements, rather than requirements] The King County board of health encourages:

1. pharmacies and collection sites to inform consumers about the safe storage and proper disposal of medicines;

2. health care providers and all other health care entities that prescribe or dispense drugs in King County to advise patients on safe storage of medicines and use of collection services for unwanted covered drugs provided through the product stewardship plans; and

3. government agencies in King County responsible for solid waste collection or disposal services to provide public education about product stewardship plans, including website information with links to producer-provided websites, through their standard communication methods with residents.

G. The local hazardous waste management program shall:

1. Promote the use of product stewardship plans and the plans' toll-free telephone numbers and web sites through their standard educational methods;

2. Provide sample educational materials for use by pharmacies, law enforcement agencies, health care providers and local government agencies in the county;

3. Provide educational materials to targeted populations and groups as informed by survey results and other research indicators; and

4. Assume the costs of developing and providing promotional and educational materials under this subsection.

NEW SECTION. SECTION 10. **Product stewardship plans – Disposal of covered drugs.**

A. Covered drugs collected under a product stewardship plan must be disposed of at a properly permitted hazardous waste disposal facility or at a properly permitted large municipal waste combustor as defined by the United States environmental protection agency under 40 CFR parts 60, 62, 264 and 265.

B. A producer or producers participating in the standard stewardship plan or an independent product stewardship plan may petition the director for approval to use final disposal technologies that provide superior environmental and human health protection than provided by the disposal technologies in subsection A. of this section, or equivalent protection at lesser cost. The proposed technology must provide equivalent or superior protection in each of the following areas:

1. Monitoring of any emissions or waste;

2. Worker health and safety;

3. Air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and

4. Overall impact to the environment and human health.

NEW SECTION. SECTION 11. **Product stewardship plans – Administrative and operational costs and fees.**

A. A producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan shall pay all administrative and operational costs related to their product stewardship plan, except as provided under this chapter. Administrative and operational costs must be financed by producers who sell covered drugs in or into King County. Administrative and operational costs related to the product stewardship plan include the following:

1. Collection and transportation supplies for each collection site;

2. Mailers and mailings if a mail-back system is developed;

3. Costs of operating take-back events if utilized, including costs of law enforcement staff time if necessary;

4. Transportation of all collected pharmaceuticals to final disposal, including costs of law enforcement escort if necessary;

5. Environmentally sound disposal of all collected pharmaceuticals under section 10 of this rule; and

6. Program promotion under section 9 of this rule.

B. The local hazardous waste management program shall purchase secure drop boxes for retail pharmacies and law enforcement agencies willing to volunteer as ongoing drop-off collection sites for the standard stewardship plan during the plan development

process and first full year of operation. Thereafter, costs of secure drop boxes are the responsibility of a producer or group of producers participating in the standard stewardship plan or an independent stewardship plan.

C. No person or producer may impose a visible fee on consumers when covered drugs are purchased or returned.

D. Staff time at ongoing collection sites at retail pharmacies and law enforcement agencies shall be provided in-kind by voluntary collectors.

NEW SECTION. SECTION 12. **Product stewardship plans – Reporting requirements.**

A. Within six months after the end of the first twelve month period of operation, and annually thereafter, the plan operator of the standard product stewardship plan and of any independent product stewardship plan shall submit a report to the director on behalf of participating producers describing their plan's activities during the previous reporting period. The report must include the following:

1. A list of producers participating in the product stewardship plan;

2. The amount, by weight, of unwanted covered drugs collected, including the amount by weight from each collection method used;

3. A list of collection sites, locations where mailers are provided, if applicable, transporters used, and the disposal facility or facilities used;

4. Whether any safety or security problems occurred during collection, transportation, or disposal of unwanted covered drugs during the reporting period and, if so, what changes have or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security in the future;

5. A description of the public education, outreach, and evaluation activities in compliance with section 9 of this rule implemented during the reporting period;

6. A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;

7. A summary of the product stewardship plan goals, the degree of success in meeting those goals in the past year, and if any goals have not been met, what effort will be made to achieve such goals in the next year; and

8. The total expenditure of the stewardship plan during the reporting period.

B. The director shall make reports submitted under this section available to the public.

C. For the purposes of this section, "reporting period" means the period commencing January 1st and ending December 31st of the same calendar year, unless otherwise specified to the plan operator by the director.

NEW SECTION. SECTION 13. **Product stewardship plans – Lists of producers of covered drugs.** Beginning in xx, 20xx [six months after R&R is passed], each drug wholesaler that sells any covered drug in or into the county must provide a list of producers of covered drugs to the local hazardous waste management program in a form agreed upon with the director. Wholesalers must update the list by January 15th of each year.

NEW SECTION. SECTION 14. **Product stewardship plans – Review of proposed plans.**

A. By xx, 20xx [one year after R&R is passed], a producer, group of producers, or stewardship organization shall submit their proposed product stewardship plan to the

director for review, accompanied by the plan review fee in accordance with section 18 of this rule. In reviewing a proposed product stewardship plan, the director shall provide opportunity for written public comment and consider any comments received from the covered drug retailers, substance abuse professionals, local governments, law enforcement, health care providers, solid waste professionals, water quality professionals, and the general public.

B. The director shall review the proposed product stewardship plan and determine whether the proposed plan meets the requirements of section 7 and other applicable sections of this rule.

C. After the review under subsections A. and B. of this section and within ninety days after receipt of the proposed product stewardship plan, the director shall either approve or reject the proposed product stewardship plan and, if rejected, provide reasons for rejection.

D. If the proposed product stewardship plan is rejected, a producer or group of producers must submit a revised product stewardship plan to the director within sixty days after receiving notice of the rejection.

E. If the director rejects a revised product stewardship plan, or any subsequently revised plan, the producer or group of producers shall be deemed out of compliance with this chapter and is subject to the enforcement provisions contained in this chapter.

F. At least every four years, the standard product stewardship plan and any independent product stewardship plan shall submit an updated plan to the director for review using the process described in subsections A., B., and C. of this section, and accompanied by the review fee in accordance with section 18 of this rule.

G. In approving a proposed product stewardship plan, the director may exercise reasonable discretion to waive strict compliance with the requirements of this chapter that applicable to producers in order to achieve the objectives of this chapter.

NEW SECTION. SECTION 15. **Product stewardship plans - Prior approval for change.**

A. Any proposed change to a product stewardship plan must have prior written approval of the director.

B. A producer or producers participating in the standard stewardship plan or any independent stewardship plan shall submit to director any proposed change to a product stewardship plan in writing and accompanied by the review fee in accordance with section 18 of this rule.

C. A producer or producers participating in the standard stewardship plan or any independent stewardship plan shall inform the director in writing of changes in collection locations in their product stewardship plan fifteen days before the changes occur. Changes in policies or procedures for collection and handling of covered drugs must be submitted in writing thirty days before the changes occur.

NEW SECTION. SECTION 16. **Product stewardship plans – Enforcement – Penalty.**

A. The director shall send a written warning and a copy of this chapter and any rules adopted to implement this chapter to a producer or group of producers who is not participating in the standard product stewardship plan or an independent product stewardship plan as required under this chapter. The warning shall state the participation requirement and warn of penalties for noncompliance.

B. A producer or group of producers not participating in the standard product stewardship plan or an independent product stewardship plan and whose covered drug continues to be sold in or into the county sixty days after receiving a written warning from the director may be assessed a penalty pursuant to subsections D. and E. of this section.

C. If the director determines that a product stewardship plan is not in compliance with this chapter or its plan approved pursuant to subsection 14 of this chapter, the director may send the producer or group of producers participating in the plan a written warning stating the plan is not in compliance, providing notice of the compliance requirements and warning of penalties for noncompliance. The producer or group of producers has thirty days after receipt of the notice to achieve compliance. If the product stewardship plan is not in compliance after thirty days, the director may assess a penalty pursuant to subsections D. and E. of this section. This subsection does not preclude the director from suspending an approved plan if a violation of this chapter or an approved plan creates a condition that, in the director's judgment, constitutes an immediate hazard.

D. A violation of this chapter is subject to a civil penalty of up to $2,000. Each day upon which a violation occurs or is permitted to continue constitutes a separate violation. In determining the appropriate penalty, the director shall consider the extent of harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action taken to mitigate the violation, the financial burden to the violator, and the size of the violator's business.

E. The director may utilize the provisions of BOH chapter 1.08 to assess civil penalties provided in this section. A producer or group of producers may appeal

assessments imposed under this section as provided in BOH chapter 1.08. In addition to or as an alternative to utilizing the procedures set forth in BOH chapter 1.08, the director may assess or recover penalties accruing under this section by legal action filed in King County superior court.

NEW SECTION. SECTION 17. **Product stewardship plans – Administrative rules, performance standards, and report.**

A. The director may adopt rules necessary to implement, administer, and enforce this chapter.

B. The director may work with the plan operator to define goals for collection amounts, education, and promotion for a product stewardship plan.

C. The director shall report annually to the King County board of health concerning the status of the standard and independent product stewardship plans and recommendations for changes to this chapter.

NEW SECTION. SECTION 18. **Plan review and annual operating fees.**

A. A producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan shall pay to the director a plan review fee for review and consultation on a proposed product stewardship plan, or on resubmittal of a proposed stewardship plan, or upon changes to an approved stewardship plan. A plan operator or a stewardship organization may remit the fee on behalf of participating producers.

B. A producer or group of producers participating in the standard product stewardship plan or an independent product stewardship plan shall pay to the director annual operating fees to cover expenses incurred administering this chapter. A plan

operator or a stewardship organization may remit the fee on behalf of participating producers.

C. As soon as practicable, the director shall propose to the board of health a schedule of fees to be charged to a producer or producers to cover costs of administering and enforcing this chapter. Fees shall not exceed actual costs.

SECTION 19. **Severability.** If any provision of this rule or its application to any person or circumstance is held invalid, the remainder of the rule or the application of the provision to other persons or circumstances is not affected.